DOCKET NO.: DM-6950 US (BMS-2204) **Application No.:** 10/033,769 **PATENT**

Office Action Dated: March 26, 2003

REMARKS/ARGUMENTS

Claims 1 to 110 are pending in this application. Restriction has been required under 35 U.S.C. § 121 between:

Group	Claims	Subject Matter	Class
I	1, 3, 4, 15, 17,	Tripodal chelant where	534/7+
	18, 27, 29, 30,	A is CR ¹	
	39, 41, 42, 51,		
	53, 54, 63-86,		
	92-110		
II	1, 3, 15, 17, 27,	Tripodal chelant where	534/7+
	29, 39, 41, 51,	A is SiR ¹	
1	53, 63-86, 92-		
	110	m: 11 1 1 1 1 1	504/7
III	1, 3, 15, 17, 27,	Tripodal chelant where	534/7+
}	29, 39, 41, 51,	A is GeR ¹	
	53, 63-86, 92-		
IV	110	Tripodal chelant where	534/7+
1	25, 27, 29-37,	A is N	334/17
	39, 41-49, 51,		
	53-61, 63-86,		
	92-110		
V	1, 3-7, 15, 17-	Tripodal chelant where	534/7+
	21, 27, 29-33,	A is P or P(O)	
	39, 41-45, 51,		·
	53-57, 63-86,		
	92-110		
VI	1, 3, 15, 17, 27,	Tripodal chelant where	534/7+
	29, 39, 41, 51,	A is $[C(L)R^2(CR^3R^4)_a]_b$	
	53, 63-86, 92-		
	110		ļ
VII	1, 3-5, 12-15,	Tripodal chelant where	534/7+
	17-19, 26-31,	A is $[N(L)C(W)(CR^5R^6)_c]_d$	
	38, 39, 41-43,		
	50, 51, 53-55,		
VIII	62-86, 92-110	Tripodal chelant where	534/7+
VIII	1, 3, 15, 17, 27, 29, 39, 41, 51,	A is $[OC(W)C(L)R^7R^8R^9)_e]_d$	334//+
	53, 63-86, 92-	A IS [OC(W)C(L)K K K Je]d	
	110		
IX	1, 3, 15, 17, 27,	Tripodal chelant where	534/7+
	29, 39, 41, 51,	A is $\{[NR^{10}C(W)C(L)R^{11}(CR^{12}R^{13})_g]_h[NR^{14}C(W)(CR^{15}R^{16})_i]_j\}$	

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Group	Claims	Subject Matter	Class
· · · · ·	53, 63-86, 92-	,	
	110		
X	1, 3, 4, 15, 17,	Tetrapodal chelant where	534/7+
	18, 27, 29, 30,	A is CR ¹	
	39, 41, 42, 51,		
	53, 54, 63-86		
XI	1, 2, 5, 15, 16,	Tetrapodal chelant where	534/7+
	27, 28, 39, 40,	A is SiR ¹	
	51, 52, 54, 63-		
	86, 92-110		
XII	1, 2, 5, 15, 16,	Tetrapodal chelant where	534/7+
	27, 28, 39, 40,	A is GeR ¹	
	51, 52, 54, 63-		
	86, 92-110		
XIII	1, 2, 5, 15, 16,	Tetrapodal chelant where	534/7+
	27, 28, 39, 40,	A is N	
	51, 63-86, 92-	·	
	110	·	
XIV	1, 2, 15, 16, 27,	Tetrapodal chelant where	534/7+
	28, 39, 40, 51,	A is P or P(O)	
	63-86, 92-110		
XV	1, 2, 15, 16, 27,	Tetrapodal chelant where	534/7+
	28, 39, 40, 51,	A is $[C(L)R^2(CR^3R^4)_a]_b$	
	63-86, 92-110		
XVI	1, 2, 15, 16, 27,	Tetrapodal chelant where	534/7+
	28, 39, 40, 51,	A is $[N(L)C(W)(CR^5R^6)_c]_d$	
	63-86, 92-110		
XVII	1, 2, 15, 16, 27,	Tetrapodal chelant where	534/7+
	28, 39, 40, 51,	A is $[OC(W)C(L)R^7R^8R^9)_e]_d$	
	63-86, 92-110		
XVIII	1, 2, 15, 16, 27,	Tetrapodal chelant where	534/7+
	28, 39, 40, 51,	A is $\{[NR^{10}C(W)C(L)R^{11}(CR^{12}R^{13})_g]_h[NR^{14}C(W)(CR^{15}R^{16})_i]_j\}$	
	63-86, 92-110		
XIX	87-89, 91	Formula where	534/7+
		A is CR ¹	
XX	87-89, 91	Formula where	534/7+
		A is SiR ¹	
XXI	87-91	Formula where	534/7+
		A is GeR ¹	
XXII	87-91	Formula where	534/7+
		A is N	
XXIII	87-89, 91	Formula where	534/7+
		A is P or P(O)	
XXIV	87-89, 91	Formula where	534/7+

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Group	Claims	Subject Matter	Class
		A is $[C(L)R^2(CR^3R^4)_a]_b$	
XXV	87-91	Formula where A is [N(L)C(W)(CR ⁵ R ⁶) _c] _d	534/7+
XXVI	87-89, 91	Formula where A is [OC(W)C(L)R ⁷ R ⁸ R ⁹) _e] _d	534/7+
XXVII	87-89, 91	Formula where A is {[NR ¹⁰ C(W)C(L)R ¹¹ (CR ¹² R ¹³) _R] _h [NR ¹⁴ C(W)(CR ¹⁵ R ¹⁶) _i] _i }	534/7+

It is asserted that the inventions of Groups I to XXVII are unrelated. A requirement has also made for an election of species, including an election of all variables associated with the chelant and either a radionuclide, heavy metal and/or biologically-active molecule.

According to MPEP § 803, there are two criteria for a proper requirement for restriction between patentably distinct inventions:

- (A) The inventions must be independent (see MPEP § 802.01, § 806.04, § 808.01) or distinct as claimed (see MPEP § 806.05-§ 806.05(i)); and
- (B) There must be a serious burden on the examiner if restriction is required (see MPEP § 803.02, § 806.04(a) § 806.04(i), § 808.01(a), and § 808.02).

For purposes of the initial requirement, a serious burden may be *prima facie* shown if the examiner shows separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02. In the subject application, the claims have been restricted into 27 different groups, however, *all 27 groups are classified in Class 534/7+*. Thus, applicants respectfully submit that a *prima facie* case of serious burden has not been established.

While applicants do not believe that a proper requirement for restriction has been established, applicants believe that any restriction among the members of the Markush groups within the claims should only be made *provisionally*. MPEP § 803.02, which addresses restriction practice with respect to Markush-type claims, clearly sets forth that the Examiner may only require a *provisional* election of a single species prior to examination on the merits. The provisional election would be given effect in the event that the Markush-type claim was found not to be allowable. Following election, the Markush-type claim would be examined fully with respect to the elected species and further to the extent necessary to determine

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patentability. If the Markush-type claim were not allowable over the prior art, examination would be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration. However, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim would then be extended.

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The MPEP provides an example in the case of an application with a Markush-type claim drawn to the compound C-R, wherein R is a radical selected from the group consisting of A, B, C, D, and E. With such a claim, the examiner may require a *provisional* election of a single species (CA, CB, CC, CD, or CE). The Markush-type claim is then examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If, on examination, the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species would be rejected, and claims to the non-elected species would be held withdrawn from further consideration. On the other hand, if no prior art anticipates or renders obvious the elected species, the search of the Markush-type claim would then be extended.

Thus, applicants respectfully request reconsideration of the requirement for restriction, and in particular an indication that the requirement is only a provisional election for the purpose of carrying out the search. Nonetheless, to be fully responsive to the restriction requirement, applicants elect with traverse to prosecute the claims of Group IV [tripodal chelant where spacer (A) is N]. Further, applicants elect with traverse a compound where spacer (A) is N; E1, E2, E3 are (CH2)_k-NHCOCH₂N(CH₂COOH)₂ [Tren(NTA)3] and where the radionuclide is 90Y.

If the Examiner is of a contrary view, the Examiner is requested to contact the undersigned attorney at (215) 557-3861.

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Date: May 15, 2003

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